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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,737	08/17/2000	Eva-Maria Mandelkow	28384/36668	5085

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/640,737

**Applicant(s)**

MANDELKOW ET AL.

**Examiner**

Olga N. Chernyshev

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37,42,44 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37,42,44 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 13, 2004 has been entered.

### ***Response to Amendment***

2. Claims 37, 42, 44 and 49 have been amended and claims 38-41 and 45-48 have been cancelled as requested in the amendment filed on December 13, 2004. Claims 37, 42, 44 and 49 are pending in the instant application.

Claims 37, 42, 44 and 49 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on December 13, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

***Sequence compliance***

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which identifies the sequences presented in Figures 1A, 3, 5 and 41, as submitted on December 13, 2004. Furthermore, in the Description of Drawings, as amended on December 13, 2004, description of Figure 10 contains a sequence, which is not properly identified also. In case these sequences are new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO: ) be made in the specification and claims wherever a reference is made to that sequence. See M.P.E.P. 2422.04.

***Drawings***

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7. It is noted that Figure 2A is referenced as 1A, which appears to be an error. Appropriate correction or clarification is required.

***Claim Rejections - 35 USC § 103***

8. Claims 37, 42, 44 and 49, as amended, stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kosik et al. in view of Harlow and Lane, 1988 for those reasons of record in section 10 of Paper mailed on June 10, 2004.

Applicant submits that “[a] “basic” and “novel” characteristic of the present invention is that the compositions and methods are useful for the production of antibodies that differentiate between tau protein that is phosphorylated at Serine 262 versus tau protein that is not” (top at page 25 of the Response). Applicant further argues that “[t]he recitation of a peptide “consisting essentially of” the specified tau amino acid sequence in the claims is entirely appropriate because it excludes materials that materially affect the peptides ability to elicit an immune response such as produce antibodies specific to an epitope comprising Serine 262” (middle at page 25). These arguments have been fully considered but are not deemed to be persuasive for the reasons that follow.

Claim 37 is directed to a composition comprising a peptide and a carrier molecule. The recited peptide is consisting essentially of a tau amino acid sequence of residues 259-267 in SEQ ID NO: 1. One skilled in the art readily understands that a peptide, by definition, is an organic molecule represented by a chain of amino acids linked together by peptide bonds. Thus, the essential structure of a peptide is defined by a specific number and order of amino acid units, such as in the recited peptide, nine amino acids having Serine at position four (or 262 within

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SEQ ID NO: 1). Further, a skilled artisan recognizes that addition of another amino acid molecule to either end of a fragment 259-267 of SEQ ID NO: 1 would, by definition, primarily and “materially affect the basic and novel characteristic(s)’ of the claimed invention” (bottom at page 24 of the Response), because it would essentially relate to a different peptide. Therefore and in accordance with MPEP 2111.03, “consisting essentially of” with respect to discrete structures, such as a peptide structure, is construed as equivalent to “comprising”. If Applicant wishes to claim a composition that is limited to a peptide of nine amino acids, which are residues 259-267 of SEQ ID NO: 1, then Applicant is advised to use a transitional phrase “consisting of”.

Furthermore, MPEP 2111 [R-1], Claim Interpretation; Broadest Reasonable Interpretation, states CLAIMS MUST BE GIVEN THEIR BROADEST REASONABLE INTERPRETATION. During patent examination, the pending claims must be "given \*>their< broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550- 51 (CCPA 1969).

Thus, as such, the broadest reasonable interpretation of the claimed composition is the one that it comprises a tau peptide (“a peptide comprising residues 259-267 in SEQ ID NO: 1”) and a carrier.

Applicant further argues that Harlow and Lane only describe coupling of peptides to a carrier protein and “one skilled in the art would not view the paired helical filaments of Kosik as “peptides” to be conjugated to a carrier molecule” (second paragraph at page 26 of the

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Response). Applicant's arguments have been carefully considered but are not persuasive for the following reasons.

As it is clear from the instant specification, as filed, the immunogenic composition of tau protein disclosed by Kosik et al. was prepared from Alzheimer's brain similarly to the protocol disclosed in the instant specification (page 45-46). One would reasonably believe that the results of the same procedure are expected to be the same. Thus, Kosik et al. disclose immunogenic composition comprising fragments of different length of a known and well-described amino acid sequence of tau peptide. Regarding the merit of the arguments, if Applicant submits that at the time of the invention the art did not teach how to conjugate the tau protein isolated from Alzheimer's brain, as described in the instant specification, to a carrier molecule, then it potentially raises the issue of lack of enablement of the claimed invention because the instant specification, as filed, does not provide a specific protocol or working examples on how to conjugate proteins derived from brain extracts to a carrier molecule.

9. Claims 37, 42, 44 and 49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vooheis, US Patent No.5, 492,812 ('812 document) for reasons of record in section 11 of Paper mailed on June 10, 2004.

Applicant argues that "one of ordinary skill in the art at the time of filing would not view the 351 amino acid polypeptide as a "peptide" to be conjugated to a carrier protein" (last paragraph at page 26 of the Response). Applicant's argument has been fully considered but is not deemed to be persuasive because the disclosure of '812 document is not limited to the full length tau peptide of SEQ ID NO: 2 but also encompasses various fragments of tau-peptides, which

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clearly could be viewed as peptides suitable for conjugation ( columns 7 and 8 of '812 document).

### ***Conclusion***

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.


Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal



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communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1646

January 19, 2005